

WinDiss32-V3

Automated Tablet Dissolution Testing and HPLC Analysis using the Agilent Chemstation™ Software - System Description and Requirements -



...unique automated solution for HPLC Dissolution Analysis



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1 General Information

The **WinDiss32-V3** HPLC option provides an analytical system for customers to configure analysis for Dissolution testing utilising Agilent Chemstation™ and 1100 LC system.

WinDiss32-V3 control Dissolution Baths, Pumps and collects samples in the Autosampler ASP2000 Workstation. These samples can be further Diluted, Mixed and injected into the Agilent 1100 LC

Peak data are acquired from Chemstation after each injection and processing and **WinDiss32-V3** calculates and plots the Dissolution profile in real time. Data is stored using **Oracle** database and data stations can be networked providing data accessibility in real time from any WinDiss32 workstation.

This Automated Tablet Dissolution Analytical System provides unprecedented performance over and above that of any other HPLC dissolution system.

- **Systems can be configured using Baths from PHARMA TEST, Erweka, Distek, Electrolab, Hanson, Sotax and Varian**
- **Automation of USP dissolution methods 1, 2, 3, 4 and 7; and not just 1 and 2 as with other systems**
- **Real time display of Dissolution data throughout the analysis, graphically and numerically**
- **After collection, samples can be diluted and treated prior to injection**
- **Uses the customers existing HPLC Chemstation methods**
- **Sample Sets or Sequence Tables are created automatically and managed by **WinDiss32-V3****
- **Reprocessing to allow for post analysis changes**
- **Re-measurement of specific Samples**
- **Automation of pH and Media change options.**

Applications are configured under the security and compliance for FDA 21 CFR part 11. This seamless implementation in **WinDiss32-V3** allows system administrators to easily manage user access rights and configure users for electronic signing

2 System Requirements

The following represents a base system only. Customers should apply for a quotation at the time of ordering or for budgeting purposes.

95-15200	WinDiss32-V3 Software Program for HPLC Sample Processing – Collection, Dilution, Mixing, Injection and HPLC measurement.
95-15157	Systems Cables for Pump and MSV
95-15163	Integrator and Auto-Zero Cable to RS8/IO
38-39000	ASP 2000 Auto Sampling Workstation
38-39002	ASP 2000 HPLC Injection Valve with Control
38-39040	MSV2X800 Media Switcher (closed loop sampling prior to dispensing (2nd. valve block and 16 channel pump if media replacement is required)
95-15162	RS8/PC Cable to ASP 2000
36-00680	IPC 8 channel peristaltic pump including pump tubing
95-15160	RS8/IO Cable to Pump
38-39020	DX-50 Single Syringe Dilutor/Dispenser
38-39081	DX-80 Eight Port Syringe Sampling/Dispenser includes 1-5 ml syringes - PTWS Pharma Test Dissolution Bath including EPE, Tablet Drop Magazine and ITM Temperature Monitoring System (Optional) PTFE Tubing Installation set Sampling Racks, Septum, Filter

From Agilent for example:

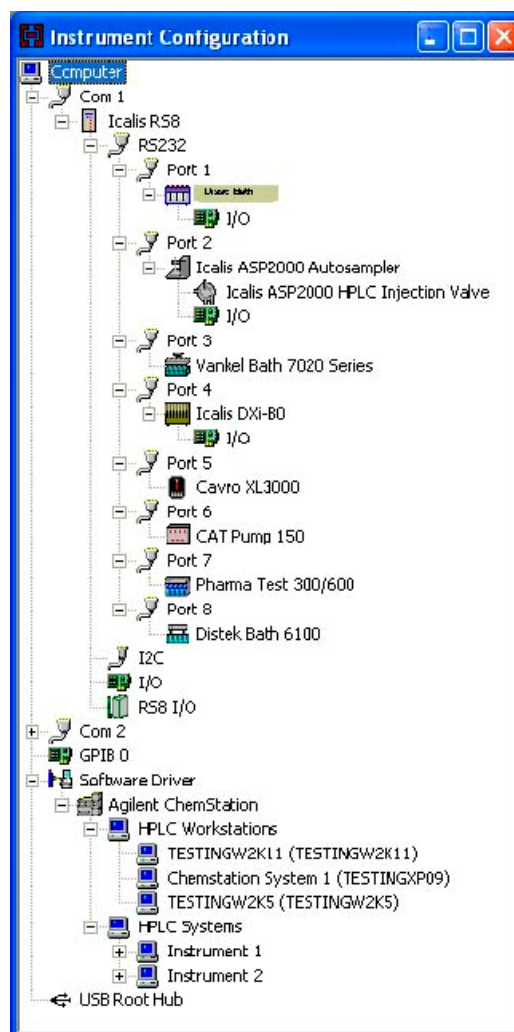
HPLC HP1100	G1310 Isocratic Pump or 1100 Pump G1314 VWD Variable Wavelength Detector Maintenance Kit for Isocratic Pump
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3 Support different Dissolution Apparatus

- **Automation of most Dissolution Tests for USP<711/724> EP <2.9.3/4> apparatus 1, 2, 3, 4 and 7**
- **Utilises many different Dissolution Baths**
- **Regulatory Compliance to 21 CFR Part 11**
- **Level of security over and above that of other dissolution system**
- **Truly open systems connectivity by dynamic linking of instruments**
- **Easily manipulated Report Organiser**
- **Data export option to LIMS**

4 Driver Linkage with unique solution path technology

- Support a wide range of Baths, Pumps and ASP2000 Analytical Processing Workstation
- Unique Solution Path Technology
- Configuration for different analysis requires no additional configuration.
- Support for Closed and Open Loop Dissolution systems.
- Collect and store Samples in ASP2000 Analytical Processing Workstation to perform online Dilution, Mixing and Injection into Chemstation™ HPLC.
- Other options include Offline sample preparation of Liquid Finished Products followed by HPLC measurement.



5 Online Dissolution Testing with Agilent Chemstation™

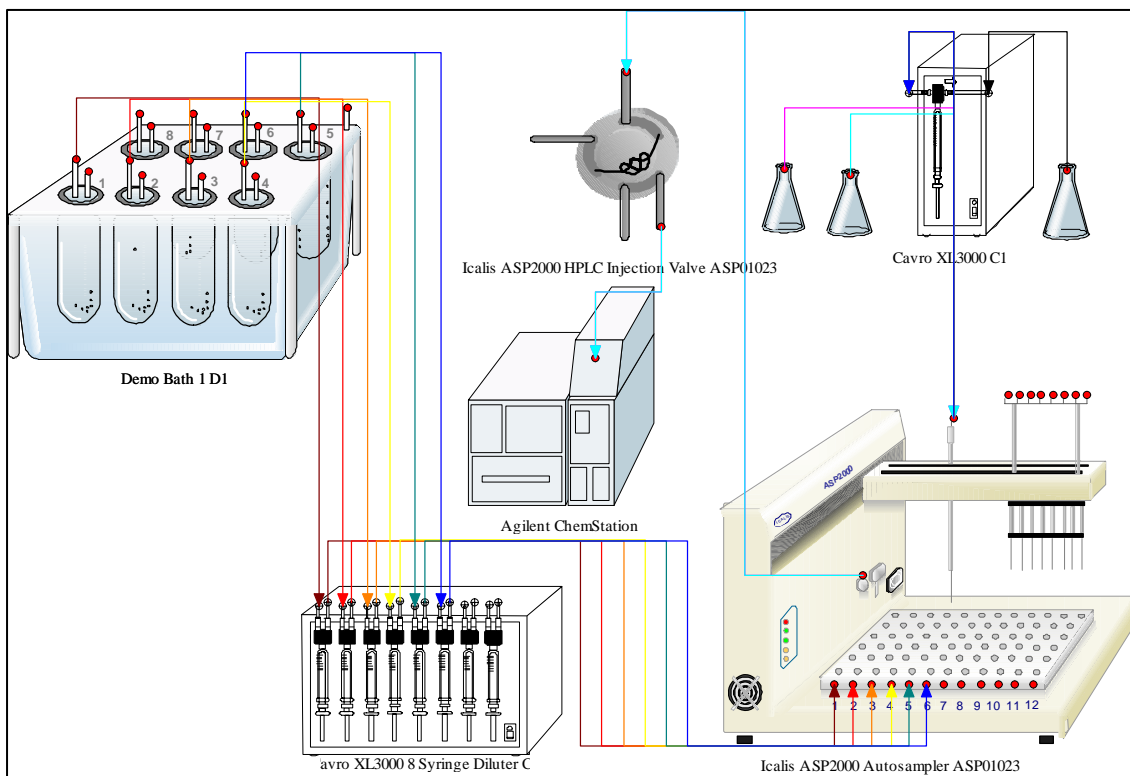
The **WinDiss32-V3** system can control nearly all dissolution Baths, Pumps, and Filter Stations with Agilent Chemstation™ HPLC.

This system configuration provides a two-way communication with the Chemstation Software. The **WinDiss32-V3** methodology is far in advance of any other HPLC dissolution system and allows for Multi-Component analysis with nearly unlimited sampling Intervals, Sample Grouping with individual group statistics for product comparison, Dilution, Mixing and Sample conditioning prior to measurement.

WinDiss32-V3 is currently the only dissolution system to allow the user to create and automate multiple pH and Media changes. Results, which comprise Area / Height values, %Dissolution, Temperature, Speed or pH etc., are displayed numerically and graphically in real time as the experiment proceeds.

During the analysis, results for each sample measured are stored in the Oracle Database thus protecting data already acquired in case of power failure.

A typical system configuration is shown below and consists of a Bath, Pump, the **ASP 2000 AutoSampler Workstation** and Chemstation™ CDS. The maximum or available functionality of each instrument is utilised. For example, Temperatures for Baths with Vessel Temperature probes will show all temperatures for each Vessel while those with only one bath probe will only display a single temperature.

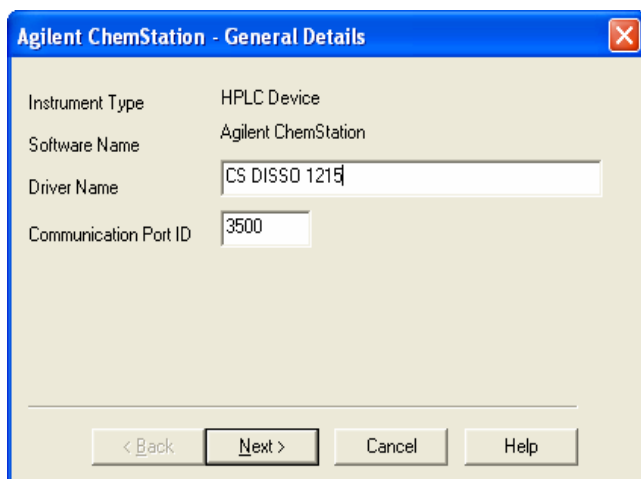


Schematic for an HPLC System, designed using WinDiss32-V3 methodology

6 Intelligent Driver Interface

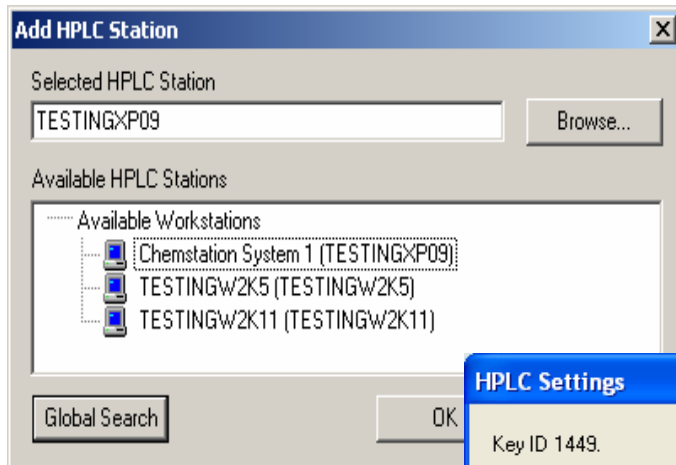
The HPLC Driver with Chemstation Software provides an intelligent two way communication using a DDE interface with Chemstation Software.

First a Driver is installed in the WinDiss32 Driver Configuration Management.



A search can be performed on the Network or a name or TCP / IP addresses can be entered to locate the Workstation(s) where Chemstation Software is installed.

Dissolution Software Program - WinDiss32-V3

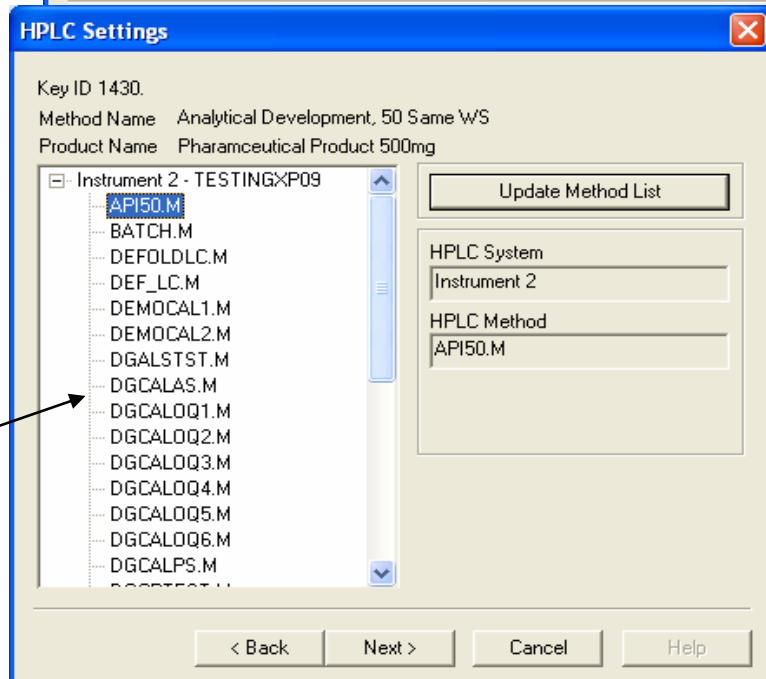
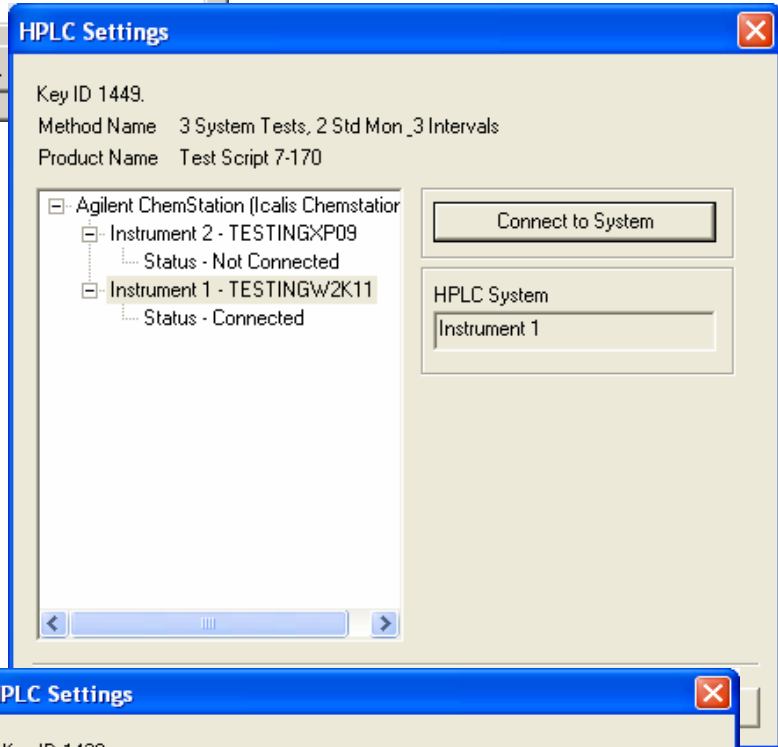


Once the workstation has been installed, a search for all HPLC Systems on the Workstation selected will occur.

At the start of the analysis, the **WinDiss32-V3** method will show all HPLC Systems installed on the workstation and will establish

communications with the Chemstation HPLC System selected.

A list of all methods on the HPLC System selected will appear. Once a method is selected for the analysis, certain parameters from the method, i.e., the processing time is acquired from the Chemstation method and used as part of the timing sequence in the analysis.



A list of the HPLC methods stored on Chemstation is acquired and displayed to the User who selects one of these methods for the analysis

This simple but effective approach makes working with **WinDiss32-V3** and Chemstation seamless, thus simplifying the whole operation.

7 Flexible Methodology

In today's world of diverse dissolution applications, **WinDiss32-V3** provides the most dynamically configured methodology to suit most customers' requirements.

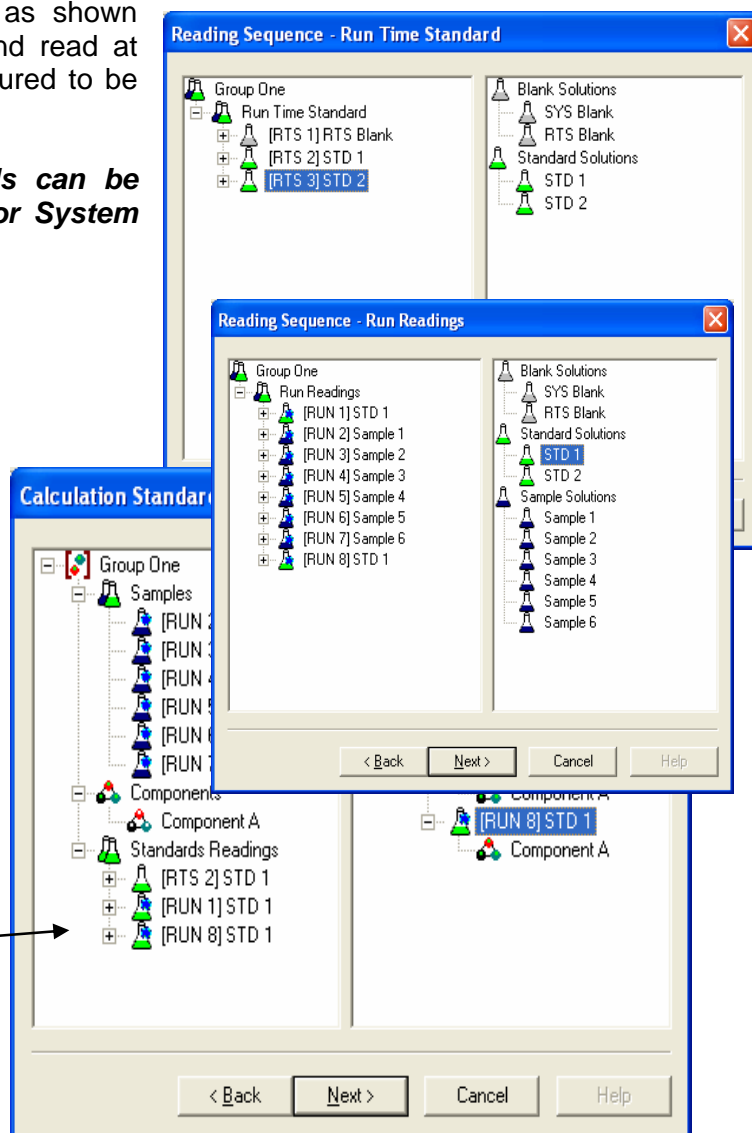
From a simple HPLC Dissolution System to systems with pH and Media change, Cell Grouping for comparative dissolution testing to running multiple dissimilar tests on one PC, the **WinDiss32-V3** has the functionality.

8 Multiple Standards with Standard Bracketing and System Suitability

Multiple Standards can be configured as shown below. Standards can be configured and read at the beginning of the analysis. Or configured to be read through the analysis.

Any combination of these standards can be used for calculation or configured for System suitability.

Standards used here for calculation are a combination of a Standard read at the beginning of the analysis and those read through the analysis. Users can configure these standards specific to their analytical requirements



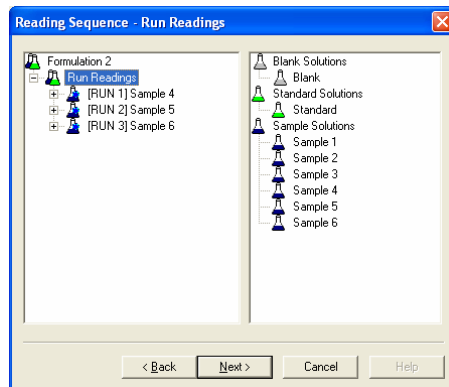
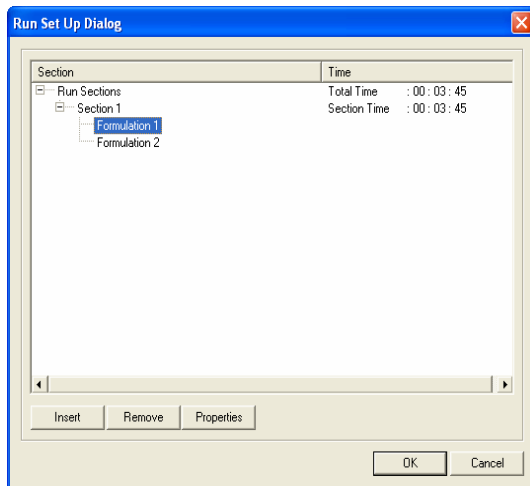
9 Acquisition of Bath Parameters

Temperature and Speed are acquired from the Bath throughout the analysis. These can be acquired more frequently than the Sampling or Time Interval.

10 Comparison of Different Testing Conditions

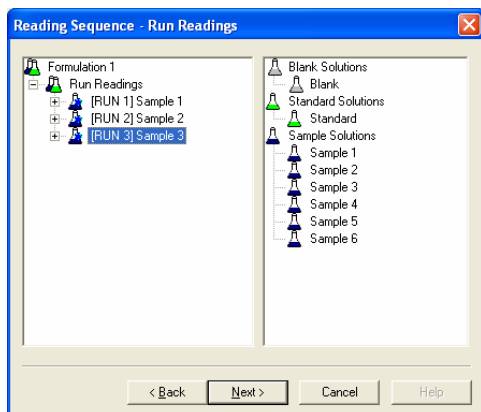
WinDiss32-V3 has many research features which are unique to our dissolution system configurations.

Users can for example group their Samples, 2 Groups of 3 Samples or 3 Groups of 2 Samples etc for comparative Dissolution Testing, for method development or comparing stability conditions where each Group can be a different product strength, from a different source and can be dissolved in a different media.



Samples for each Group in a different media, can have a different Volume, Wavelength and can use a standard appropriate to the media for the Group.

Opposite and above, 2 Groups, **Formulation 1** and **Formulation 2** each have 3 Samples configured.

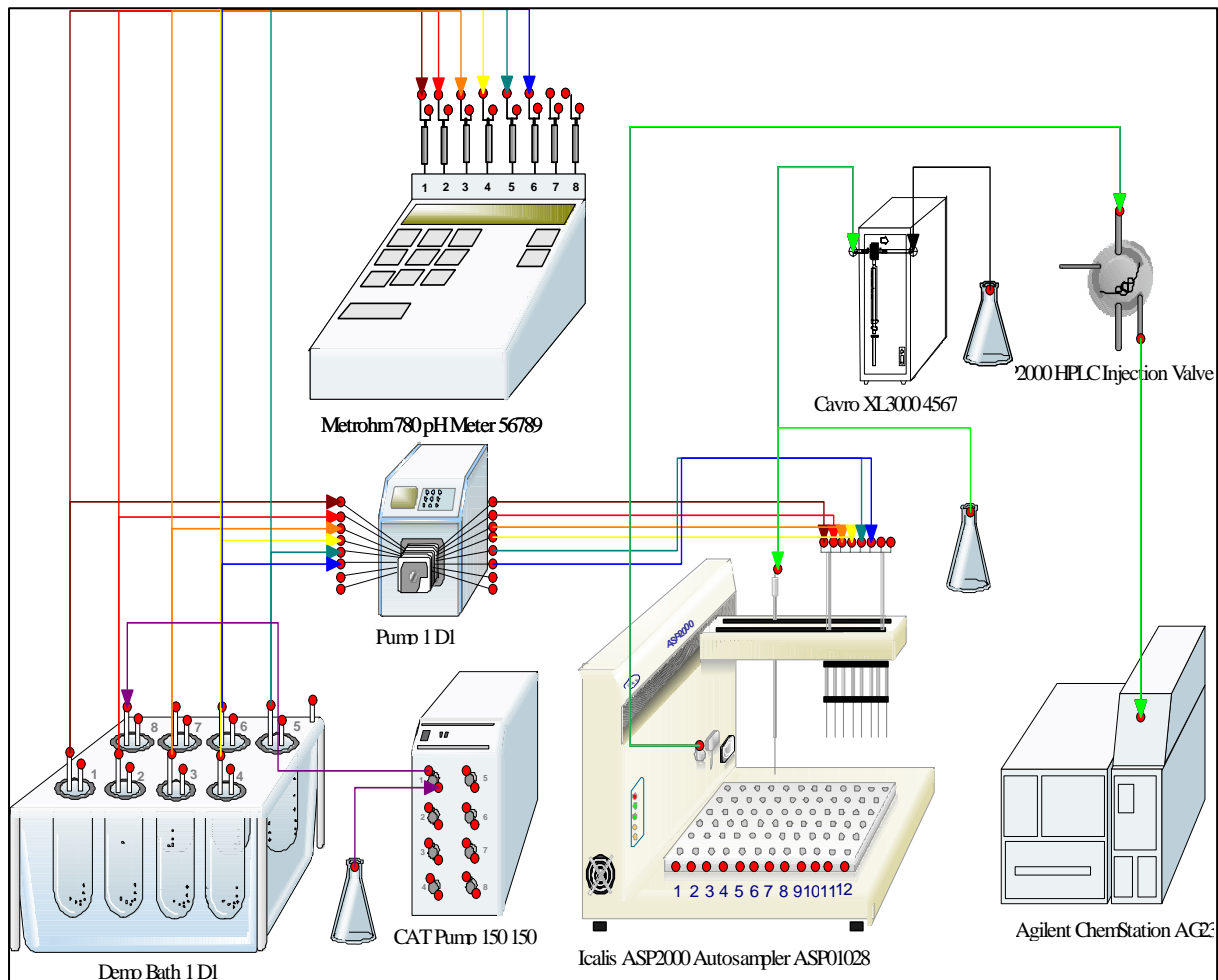


11 HPLC Analysis with pH Change by Media Addition and or Removal

WinDiss32-V3 provides the most advanced functionality for changing the pH throughout the experiment. Systems for Discrete or Gradient Media Addition can be configured with Media removal to allow for a single or multiple Media Change during the analysis, results calculated and displayed in real time.

For a full Media change, the user will be prompted when a full change is occurring and the experimental timer can be configured to halt until the change has occurred. This will allow you to comply with the USP for 2% maximum deviation for dissolution times.

The sequences for all instruments are controlled by **WinDiss32-V3**



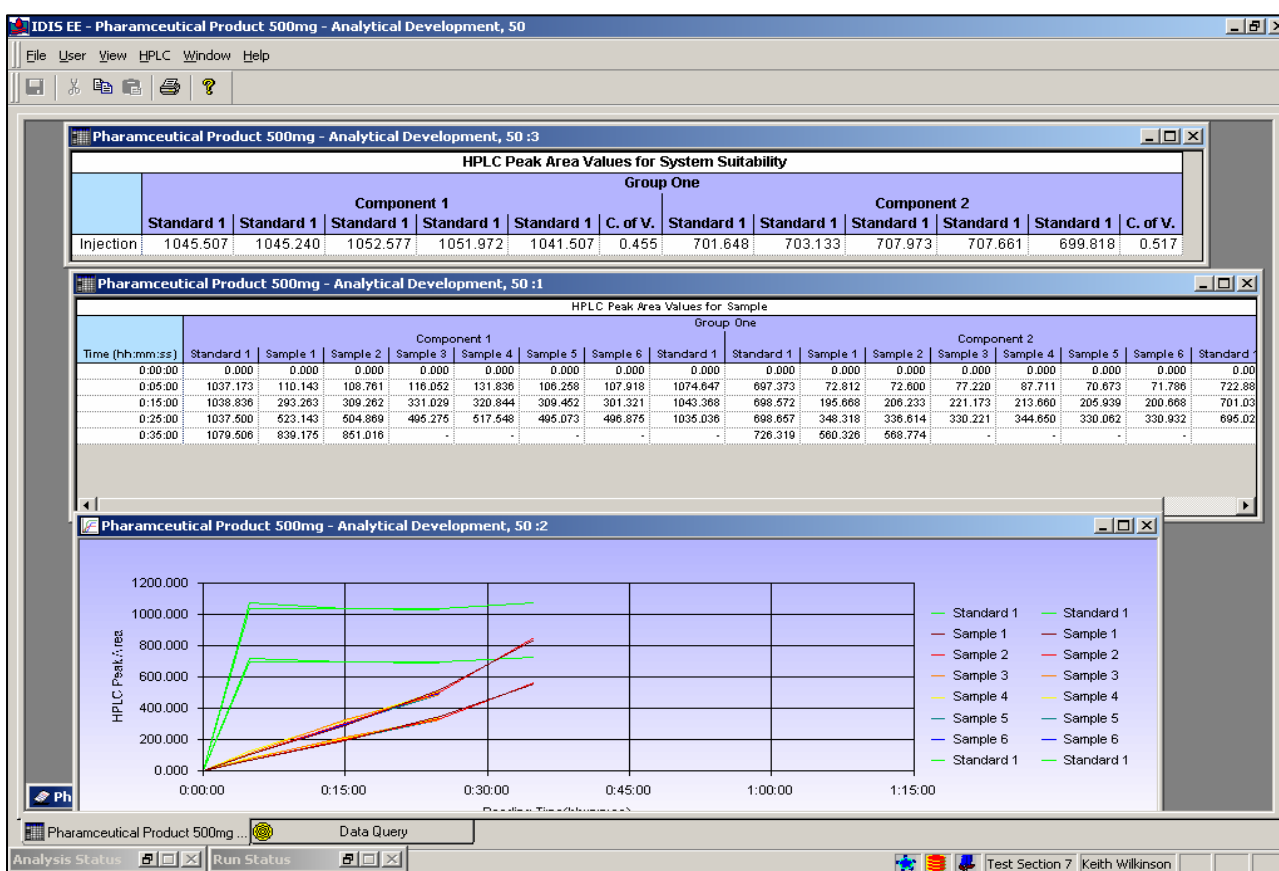
Schematic for an HPLC configuration with Media Change and pH measurement. Designed using WinDiss32-V3 methodology

12 System Control and Real Time Display of Results

The **ASP 2000 Auto Sampler Workstation** allows simultaneous operations for Sampling, Dilution, and Injection into a Chemstation LC system. After each injection, Chemstation perform the processing and the integrated values or results are acquired from the Chemstation System. The dissolution profile is updated and displayed numerically and graphically in real time on **WinDiss32-V3** workstations.

There is no need for any manual intervention once this system has started.

Using a special Deferred Data Collection™ sequence, Samples Collected can be Diluted, Mixed and Injected while still maintaining accurate Collection times, thus delivering analysis in faster time periods.



Dissolution data Area values for two Components for a pharmaceutical product. The data is cached to the Oracle database as soon as it is collected.

Data, Area / Height values, Temperature, Speed and pH if configured, which are acquired during the analysis, are displayed in real time as shown above. From the Area / Height values, the %Dissolution is calculated and displayed in real time.

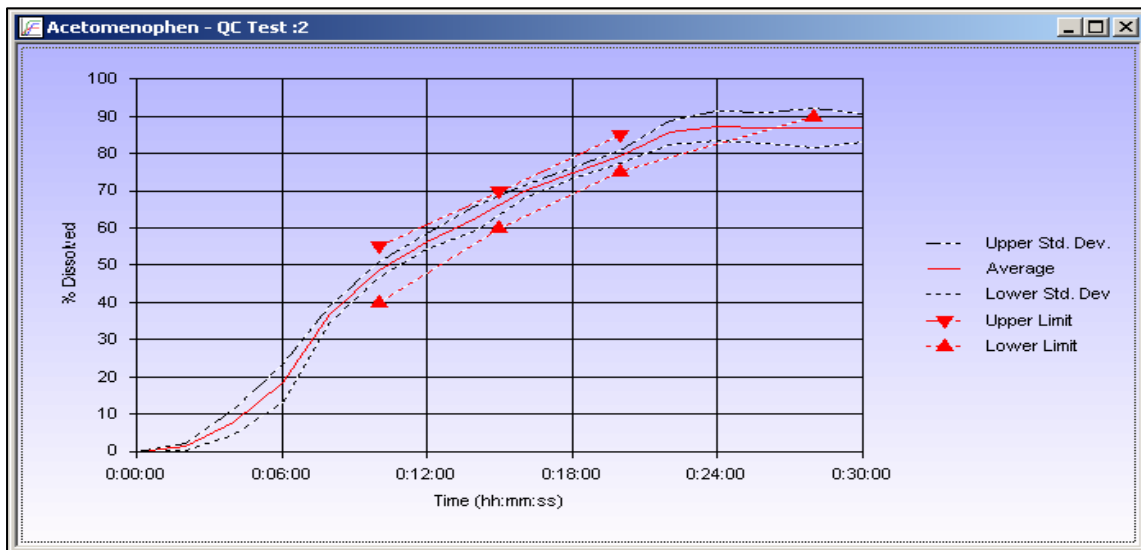
If the systems are networked, results on any workstation can be loaded remotely on any other **WinDiss32-V3** workstation.

13 Display of Compliance Table and Ranges Graphically

During the analysis or after the test has completed, the compliance table indicating whether the test has passed or failed can be displayed graphically or numerically. This is a very important tool for Quality Control and for Stability studies.

Acetomenophen - QC Test :1									
Specification 1 (USP - % Dissolved)									
Time (hh:mm:ss)	Lower	Upper	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Pass / Fail
0:10:00	40.00	55.00	47.09	46.74	47.09	49.88	50.58	51.28	Pass
0:15:00	60.00	70.00	65.93	68.20	68.55	67.50	62.97	63.66	Pass
0:20:00	75.00	85.00	80.58	78.84	76.40	80.58	78.49	80.58	Pass
0:28:00	90.00	-	90.70	90.00	76.74	88.26	85.47	89.65	Fail

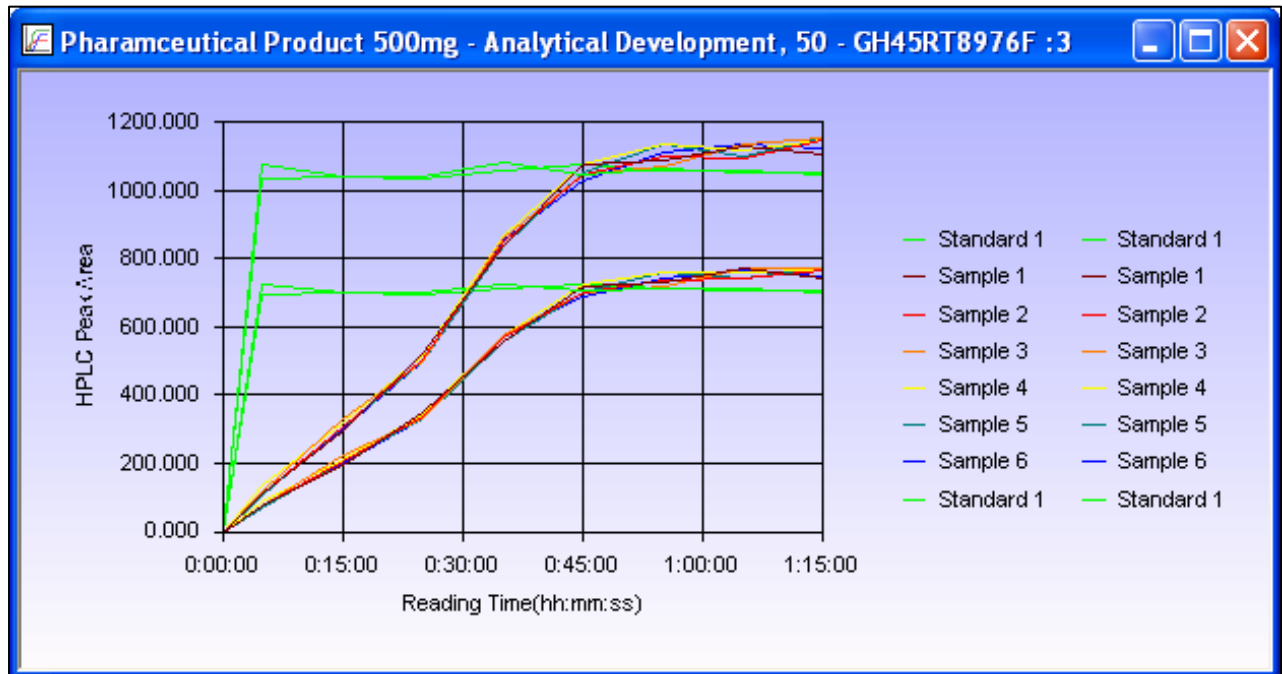
Specification Compliance Table – Multiple Specifications can be configured for different pharmacopoeia requirements



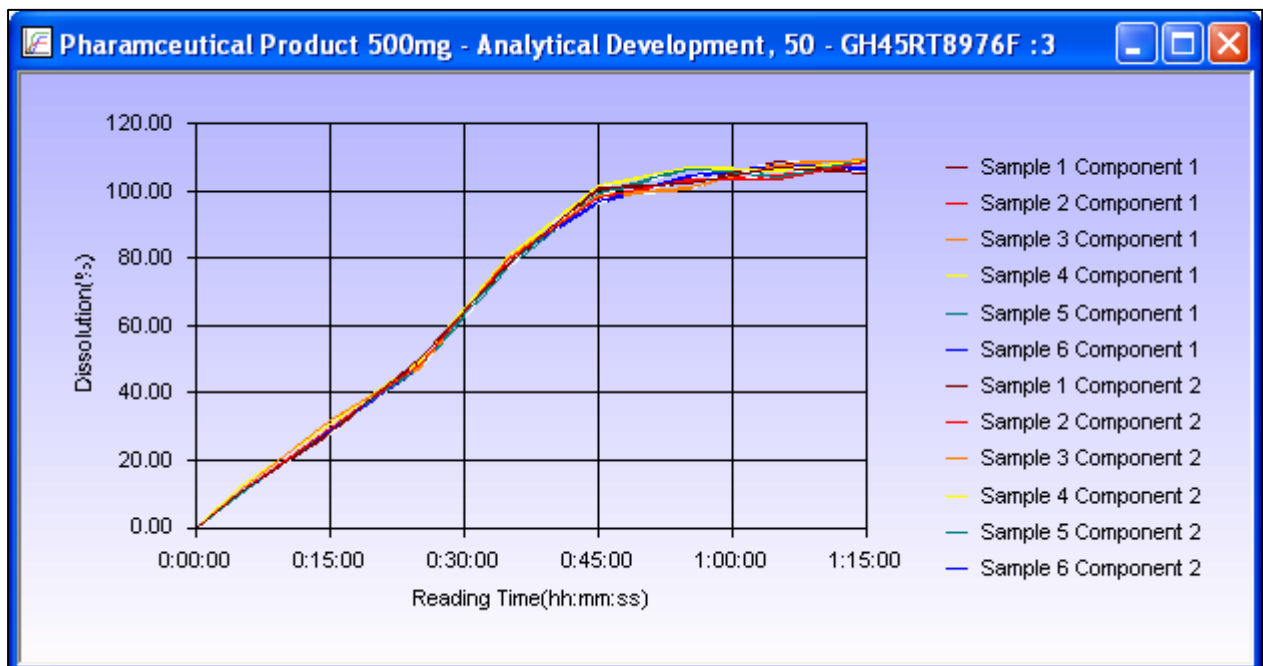
Graphical display of Specification Compliance

14 Multiple Component Analysis

Multiple Component analysis can be performed. Below, the raw Area data for two components are displayed in real time.



The resultant %-Dissolution data can also be displayed numerically and graphically for each component.



15 Data for Different Groups can be Displayed with Individual Statistics

When data for analysis with multiple groups are displayed, the groups are displayed separately as though they are dissimilar tests, each with their own statistics. This allows analysis of the quality of the data from each group without having to export data into Excel, for example.

First Group of Samples with their statistics

Second Group of Samples with their statistics

Sample Dissolution Values										
Time (hh:mm:ss)	Stability Group 1					Stability Group 2				
	Sample 1	Sample 2	Sample 3	Mean	S.D.	Sample 4	Sample 5	Sample 6	Mean	S.D.
0:00:00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
0:00:15	7.72	6.95	4.25	6.31	1.82	7.72	10.81	11.58	10.04	2.04
0:00:30	17.37	16.60	25.10	19.69	4.70	27.41	18.15	13.51	19.69	7.08
0:00:45	38.61	41.70	42.86	41.06	2.20	38.61	41.70	38.61	39.64	1.78
0:01:00	52.12	52.51	52.51	52.38	0.22	54.44	52.51	57.14	54.70	2.33
0:01:15	60.62	60.23	64.48	61.78	2.35	61.00	61.78	63.32	62.03	1.18
0:01:30	68.73	72.20	74.13	71.69	2.74	70.66	60.62	66.41	65.89	5.04
0:01:45	77.22	80.31	78.38	78.64	1.56	77.22	71.81	75.29	74.77	2.74
0:02:00	85.33	84.17	82.24	83.91	1.56	81.47	79.15	80.69	80.44	1.18
0:02:15	89.19	88.03	84.94	87.39	2.20	88.42	83.40	89.58	87.13	3.28
0:03:00	100.39	96.53	88.42	95.11	6.11	96.91	91.89	100.00	96.27	4.09
0:03:15	100.39	100.39	85.33	95.37	8.69	96.91	91.12	99.61	95.88	4.34
0:03:30	100.39	95.75	89.19	95.11	5.63	96.91	91.89	100.39	96.40	4.27

All Baths configured will be controlled automatically. Details such as Temperature, Speed and in some cases pH are acquired during the analysis and can be displayed to the user in real time. Collection of other data such as the Bath Temperature and Speed

Sample Temperature Values								
Time (hh:mm:ss)	Group One						Mean	C. of V.
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6		
0:05:00	36.5	36.5	36.5	36.5	36.5	36.5	36.5	0.0
0:15:00	36.5	36.5	36.5	36.5	36.5	36.5	36.5	0.0
0:25:00	36.5	36.5	36.5	36.5	36.5	36.5	36.5	0.0
0:35:00	36.5	36.5	36.5	36.5	36.5	36.5	36.5	0.0
0:45:00	36.5	36.5	36.5	36.5	36.5	36.5	36.5	0.0
0:55:00	36.5	36.5	36.5	36.5	36.5	36.5	36.5	0.0
1:05:00	36.5	36.5	36.5	36.5	36.5	36.5	36.5	0.0
1:15:00	36.5	36.5	36.5	36.5	36.5	36.5	36.5	0.0

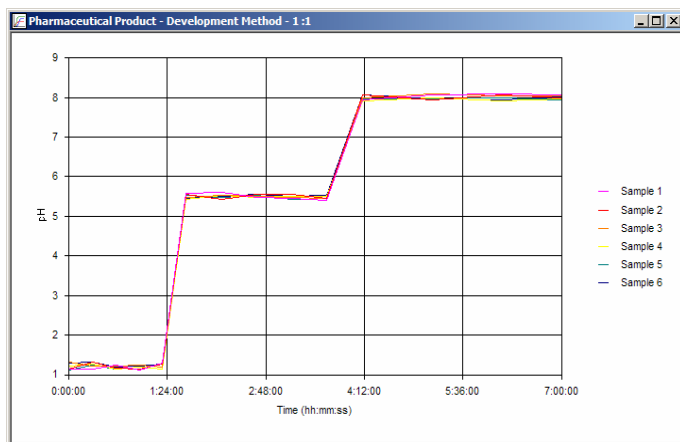
16 Monitoring pH and Dissolution Data Simultaneously

During the experiment for pH change methods, readings are taken at multiple time points and **WinDiss32-V3** displays and monitors Absorbance, pH, Temperature and Speed as well as calculating the %-Dissolution in real time.

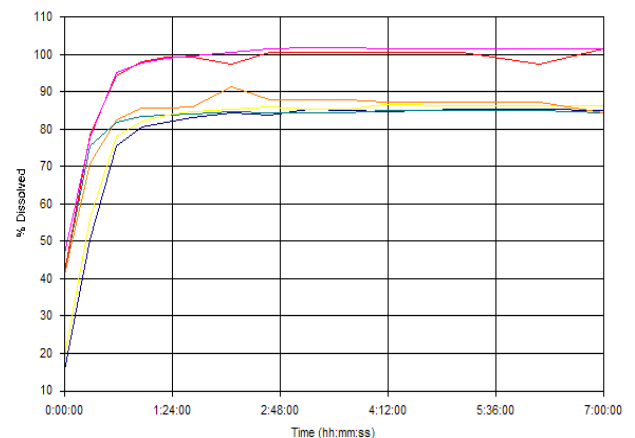
At specific times set by the user, readings are taken and the pH, Absorbance and %-Dissolved profile are plotted in real time.

Graphs can be displayed simultaneously for all data types (pH, Absorbance, %-Dissolved etc) during and after the analysis is completed.

Graph showing a pH profile obtained from monitoring the pH in a method with 3 Media Change.



Corresponding % Dissolve Data Graph



17 Dynamic Report Editor

The **WinDiss32-V3** report organiser allows users to produce customised reports with the required information by selecting from a combination of objects such as Method Header, Data tables, Method parameters, Graphs and the company logo.

Refer to a typical report on page 20.

These details include method parameters as well as any data captured during the test such as bath Temperature, Paddle speed, Time Intervals as well as Absorbance, Concentration and % Dissolved.

Any number of pages can be selected with automatic page numbering.

18 Reprocessing and Re-measurement

WinDiss32-V3 allows the user to acquire results for Samples after Reprocessing in Chemstation and to Re-measure Samples for those situations when some of the vials are not injected properly, for example.

WinDiss32-V3 stores the reference ID's for all LC peak data acquired from Chemstation.

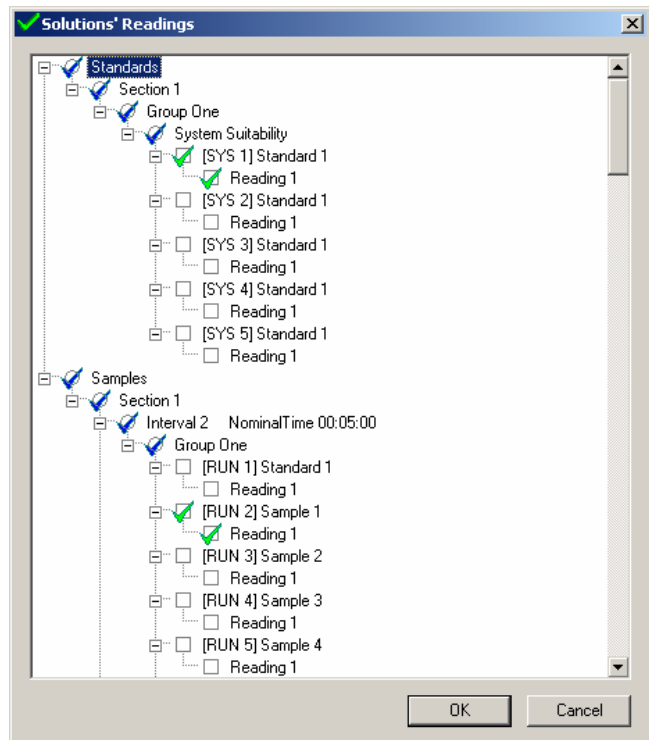
ID's in WinDiss *integrated solutions* above and opposite, the same ID's in Chemstation

HPLC Data ID for Sample									
Experiment Name									
Experiment ID	28011547								
Time (hh:mm:ss)	Group One Component 1								
	Standard 1 R 1	Sample 1 R 1	Sample 2 R 1	Sample 3 R 1	Sample 4 R 1	Sample 5 R 1	Sample 6 R 1	Standard 1 R 1	
0:05:00	006-0101.D	007-0101.D	008-0101.D	009-0101.D	010-0101.D	011-0101.D	012-0101.D	013-0101.D	
0:15:00	014-0101.D	015-0101.D	016-0101.D	017-0101.D	018-0101.D	019-0101.D	020-0101.D	021-0101.D	
0:25:00	022-0101.D	023-0101.D	024-0101.D	025-0101.D	026-0101.D	027-0101.D	028-0101.D	029-0101.D	
0:35:00	030-0101.D	031-0101.D	032-0101.D	033-0101.D	034-0101.D	035-0101.D	036-0101.D	037-0101.D	
0:45:00	038-0101.D	039-0101.D	040-0101.D	041-0101.D	042-0101.D	043-0101.D	044-0101.D	045-0101.D	
0:55:00	046-0101.D	047-0101.D	048-0101.D	049-0101.D	050-0101.D	051-0101.D	052-0101.D	053-0101.D	
1:05:00	054-0101.D	055-0101.D	056-0101.D	057-0101.D	058-0101.D	059-0101.D	060-0101.D	061-0101.D	
1:15:00	062-0101.D	063-0101.D	064-0101.D	065-0101.D	066-0101.D	067-0101.D	068-0101.D	069-0101.D	

This referential integrity allows identification of peaks on Chemstation when Reprocessing or Remeasurement is selected. Once results have been reprocessed on Chemstation, the **WinDiss32-V3** data record is loaded and Reprocessing selected.

The records in Chemstation are identified and the new results acquired. This data can be saved in the **WinDiss32-V3** database and thereafter it is identified as Post Edited data.

For Re-measurement, a clear unambiguous dialog (shown opposite) appears to the user for selection of those solutions (Standards or Samples) to be measured again.



19 FDA 21 CFR part 11 Compliance

Administration management allows the system administrator to configure **WinDiss32-V3** to meet one of the fullest implementation of 21 CFR Part 11 compliance of any data management system available today.

Individual access to the system is by a unique user name and password, configured for each user with Group or individual access rights, and the users full name is displayed when the user logs on successfully and on all documentation generated by the system for the user.

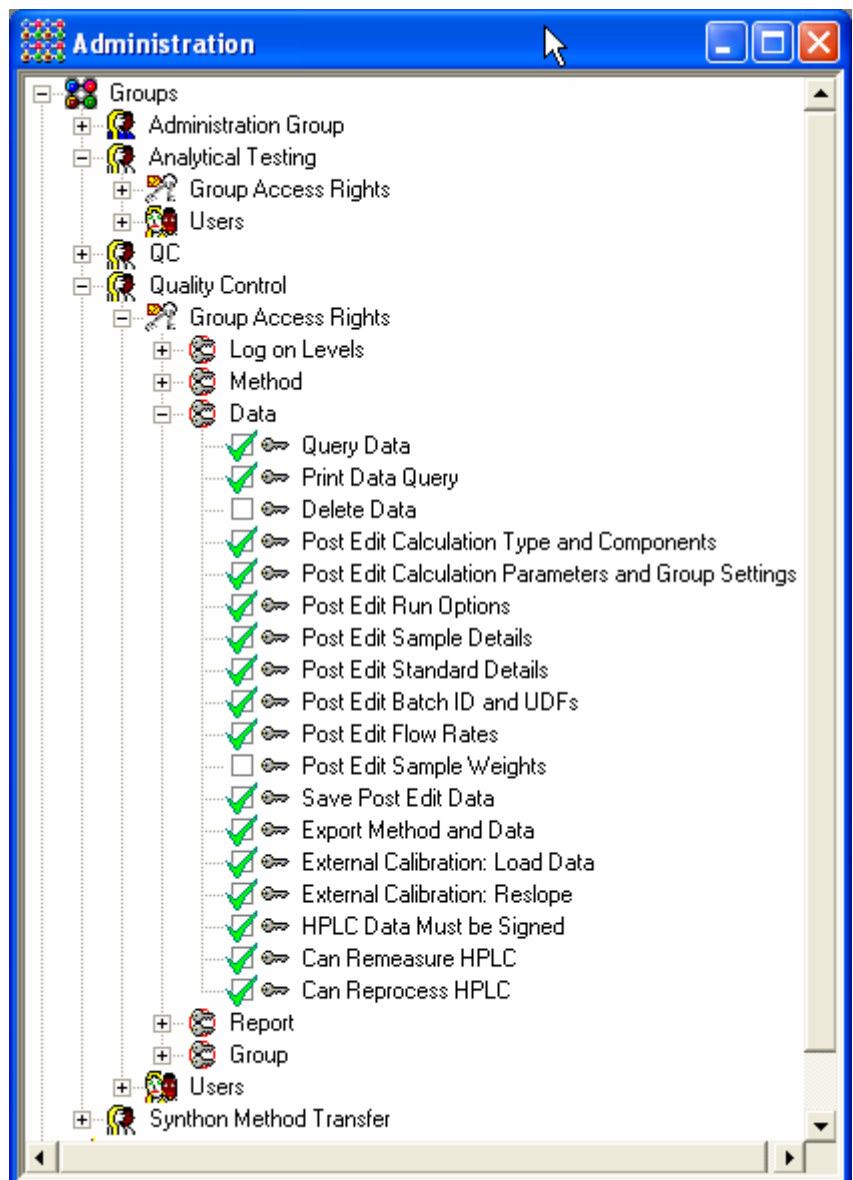
Configurable Centralised Security

Functionality is provided to allow the administrator to set limits to control the security of the network environment for **WinDiss** workstations.

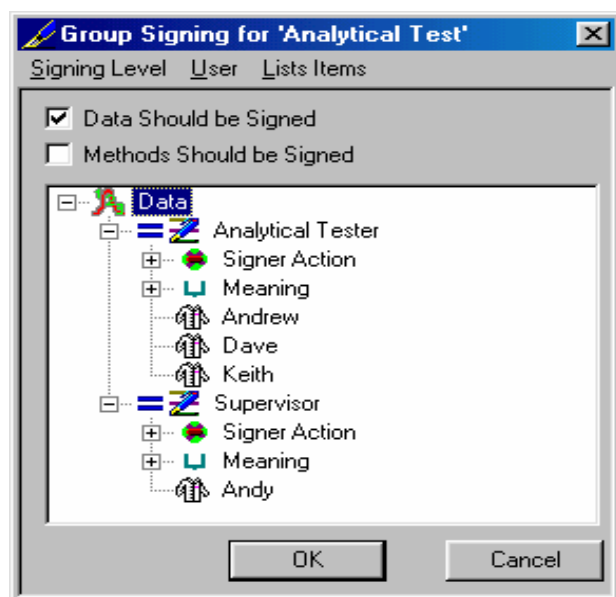
The system administrator can manage password expiry and Reuse, Log Off Times and text to instruct users in their local language what to do in case of access failure, etc.

These activities can be performed remotely from any **WinDiss32-V3** networked workstation and only ever need to be performed once for each user.

With other systems that are not networked, this procedure would have to be repeated for each workstation.

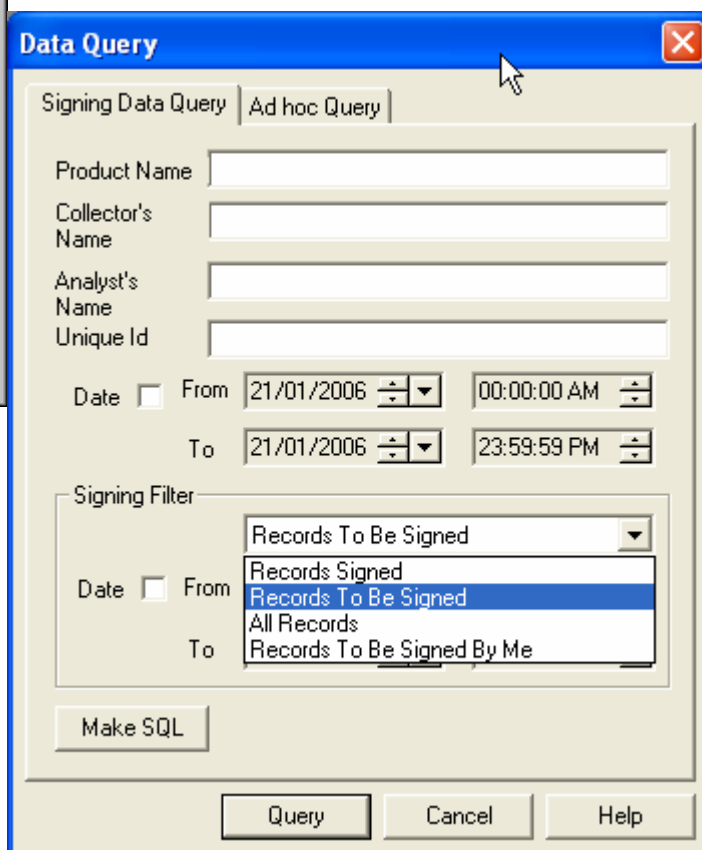


20 Signing and Tracking Signature on Records



The administrator can use up to 5 signature levels appropriate to the structure of the company. These levels can be for Analysts, Supervisors and Qualified personnel.

WinDiss32-V3 provide total management for signing, from start to finish. Configuring the number of signing levels, the Users for each level, Signer Activity and Meaning are all managed by the company's administrator.



Once the analysis is completed the signing of records can be performed. For HPLC analysis with certain Chromatography Data Systems, no signing can be performed until the records on the CDS are signed.

Records will only be displayed automatically for the Groups the user logging on for signing belongs to and further filtering of records, to limit the number displayed, is provided using the Signing Query dialogue shown above.

Dissolution Software Program - WinDiss32-V3

Once data is acquired in a Group configured for signing, a summary of records to be signed can be obtained and records for signing are clearly visible in dark blue with red indicating the signing for other levels.

Single or multiple record(s) can be signed in any one session.

The screenshot shows the IDIS EE software window with a menu bar (File, User, View, Window, Help) and a toolbar. The main area contains a table with the following data:

Key Field	Product Name	Batch Id	Collected Date/Time	Group Name	Signing Status	Signing Level	Signer Action	Meaning
68	Acetomenophen 500mg	TR3267HG	21/01/2006 16:57:01	Analytical Testing	Partially Signed Off	Supervisor Signing Level	N/A	N/A
68	Acetomenophen 500mg	TR3267HG	21/01/2006 16:57:01	Analytical Testing	Partially Signed Off	Tester Signing Level	Tested by	Analyst Sign Off
67	Acetomenophen 500mg	TR327Y	21/01/2006 16:50:54	Analytical Testing	Not Signed	Supervisor Signing Level	N/A	N/A
67	Acetomenophen 500mg	TR327Y	21/01/2006 16:50:54	Analytical Testing	Not Signed	Tester Signing Level	N/A	N/A
66	System Test RT's Comparison	run 1	14/01/2006 12:02:53	Analytical Testing	Not Signed	Supervisor Signing Level	N/A	N/A
66	System Test RT's Comparison	run 1	14/01/2006 12:02:53	Analytical Testing	Not Signed	Tester Signing Level	N/A	N/A
65	System Test - 1Blank 1 RTS	tyrers	13/01/2006 14:08:48	Analytical Testing	Not Signed	Supervisor Signing Level	N/A	N/A
65	System Test - 1Blank 1 RTS	tyrers	13/01/2006 14:08:48	Analytical Testing	Not Signed	Tester Signing Level	N/A	N/A
64	Content Uniformity Method	B&4565	15/12/2005 14:44:54	Analytical Testing	Partially Signed Off	Supervisor Signing Level	N/A	N/A
64	Content Uniformity Method	B&4565	15/12/2005 14:44:54	Analytical Testing	Partially Signed Off	Tester Signing Level	Tested by	Analysst Checked Results
63	Acetomenophen	B435	15/12/2005 10:14:52	Analytical Testing	Not Signed	Supervisor Signing Level	N/A	N/A

The signing process is very simple, clear and precise, the User must view the records selected (which they have access to sign) before the User can sign these records.

Once the records are eligible for signing, Signer Action and Meaning are selected from a list of predefined Actions and Meaning then the user name and password are required to complete signing.

The 'Signing Settings' dialog box contains the following fields:

- Signer Action:** A dropdown menu with 'Tested by' selected.
- Meaning:** A dropdown menu with 'Analyst Sign Off' selected.
- Log On Name:** A text input field containing 'denise'.
- Password:** A text input field with masked characters 'xxxxxxxx'.

At the bottom of the dialog are 'OK' and 'Cancel' buttons.

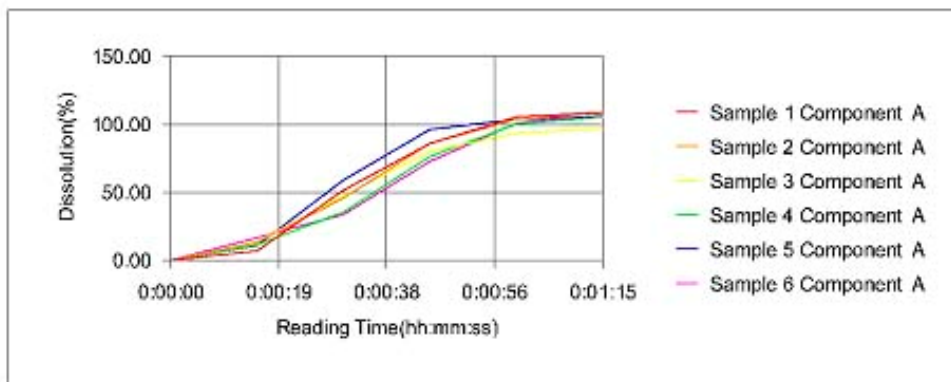
Once records are signed, the signing is clearly shown on the footer of each page, as they would appear for manual conventional signatures.



Product Name	: Acetomenophen 500mg tablets
Method Name	: Stability Test
Batch ID	: TR4543SD
Method Group	: Group One
Group Name	: Test Section 8
Data Collection	
User Name	: Keith Wilkinson
Station Name	: TESTINGXP09
Date - Time	: Saturday, January 21, 2006 17:55:43
Acquired by Version	: IDIS EE v2.20.00 B30
Current Version	: 2.20.00 B30
Data Key Field	: 1837
Data Occurrence	: 1
Data Unique ID	: 95F27496-5146-42CD-ABBC-509727E5EA92

Absorbance Values for Sample (A Units)								
Group One								
Time (hh:mm:ss)	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Mean	S.D.
Section 1								
Wavelength (285 nm)								
0:00:00	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
0:00:15	0.016	0.031	0.032	0.027	0.025	0.039	0.028	0.008
0:00:30	0.120	0.106	0.110	0.082	0.137	0.079	0.106	0.022
0:00:45	0.200	0.200	0.186	0.177	0.224	0.169	0.193	0.020
0:01:00	0.245	0.241	0.217	0.233	0.240	0.234	0.235	0.010
0:01:15	0.252	0.251	0.225	0.244	0.244	0.247	0.244	0.010

Sample Dissolution Values								
Group One								
Time (hh:mm:ss)	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Mean	S.D.
0:00:00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
0:00:15	6.90	13.36	13.79	11.64	10.78	16.81	12.21	3.34
0:00:30	51.72	45.69	47.41	35.34	59.05	34.05	45.55	9.59
0:00:45	86.21	86.21	80.17	76.29	96.55	72.84	83.05	8.49
0:01:00	105.60	103.88	93.53	100.43	103.45	100.86	101.29	4.27
0:01:15	108.62	108.19	96.98	105.17	105.17	105.47	105.10	4.24



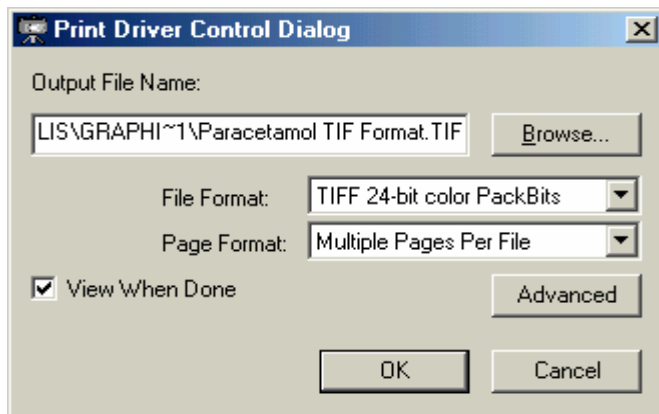
Analyst : Tested By Keith Wilkinson 21/01/2006 18:04:33 Analyst Sign Off
 Signing Level "Supervisor" Requires Signing.

The status of signing is clearly shown on IDIS reports.

21 Non-Editable Graphic Electronic Records

WinDiss32-V3 is supplied with the IC Graphics Printer that provides compliance with 21 CFR Part 11 requirements for “human readable form”.

These reports can be circulated, emailed etc., in the safe knowledge that they are non-editable.



The Graphics Printer can capture any **WinDiss32-V3** report into TIF, BMP or JPG (JPEG) and save them as electronic files.

The TIF format can save a multiple page report and the Image Viewer supplied automatically displays the printed file image for verification.

22 User Queryable Audit Trail and Record History

WinDiss32-V3 Audit Trail lists all user activity that creates, deletes or modifies; i.e., from logging on and off to editing of method and data records.

This Audit Trail can have filters to limit the volume of information from a search. The results from any search can be printed.

Audit Trail Filters

The screenshot shows the 'Audit Trail Query' window. On the left, there is a tree view under 'Change Type' with the following items: Data, Database Error, Device Management, Global Setting, Instrument Configuration, Method, Method Types, Post Edit, Run, Signing, Station Locking, System Administration, and System Log On Status. An arrow points from the text 'Audit Trail Filters' to this tree view. The main area is a table with the following columns: Key Field, User Name, Change Type, and Change Comment. The table contains numerous rows of audit trail data, including entries for 'Administrator', 'Keith Wilkinson', and 'Clive Wardle' performing various actions like 'Global Setting', 'System Log On Status', 'Run', and 'Method'.

Key Field	User Name	Change Type	Change Comment
397	Administrator	Global Setting	Application Log Off Time set to 4hrs 2mins
396	Administrator	Global Setting	Approval Log Off Time set to 0hrs 15mins
395	Administrator	Global Setting	Device management Log Off Time set to 0hrs 30mins
394	Administrator	System Log On Status	User log on successful to level "Administration" in group "Administration Group"
393	Keith Wilkinson	System Log On Status	User Logged Off
392	Keith Wilkinson	System Log On Status	User log on successful to level "Application" in group "Test Section 9"
391	Administrator	System Log On Status	User Logged Off
390	Administrator	System Administration	Group "Test Section 9" has had the right taken away "Data : Query Data"
389	Administrator	System Log On Status	User log on successful to level "Administration" in group "Administration Group"
388	Keith Wilkinson	System Log On Status	User Logged Off
387	Keith Wilkinson	System Log On Status	User log on successful to level "Application" in group "Test Section 9"
386	Administrator	System Log On Status	User Logged Off
385	Administrator	System Log On Status	User log on successful to level "Administration" in group "Administration Group"
384	Administrator	System Log On Status	User Logged Off
383	Administrator	System Log On Status	User log on successful to level "Administration" in group "Administration Group"
382	Administrator	System Log On Status	User Logged Off
381	Administrator	System Log On Status	User log on successful to level "Administration" in group "Administration Group"
380	Administrator	System Log On Status	User Logged Off
379	Administrator	System Log On Status	User log on successful to level "Administration" in group "Administration Group"
378	Keith Wilkinson	System Log On Status	User Logged Off
377	Keith Wilkinson	Run	Run started for Data ID "SED3EFA2-BC84-4DBC-B954-8764873F711B"
376	Keith Wilkinson	System Log On Status	User log on successful to level "Application" in group "Default Group"
375	Keith Wilkinson	Run	Run aborted by user for Data ID "2DA81D9F-CA41-49E5-9C89-2429C3F54956"
374	Keith Wilkinson	System Log On Status	User log on successful to level "Application" in group "Default Group"
373	Clive Wardle	System Log On Status	User Logged Off
372	Clive Wardle	Run	Run started for Data ID "717BC9FB-EB1D-4192-A6A9-8453CA171F4F"
371	Clive Wardle	Method	BF033D89-8507-419B-9690-A475E34D2AF6:Method Labels:"Product Name" set to "Log off set to 2 mins Test" in
370	Clive Wardle	Method	BF033D89-8507-419B-9690-A475E34D2AF6:Method Re-saved: Changing its ID from "A933D0A0-D71F-4BB0-AF-
369	Clive Wardle	System Log On Status	User log on successful to level "Application" in group "Default Group"
368	Administrator	System Log On Status	Log On Failed "clive" logging on to level "Application" in group "Default Group".
367	Administrator	System Log On Status	User Logged Off
366	Administrator	Global Setting	Application Log Off Time set to 0hrs 2mins
365	Administrator	System Log On Status	User log on successful to level "Administration" in group "Administration Group"
364	Keith Wilkinson	Run	Run started for Data ID "12517A98-CDCB-40A3-B2D9-E2F585639FCB"
363	Keith Wilkinson	Method	A933D0A0-D71F-4BB0-AF1B-99E9FF741832:Calculation Details:Run Sections:Section 1:"Number of Readings" s
362	Keith Wilkinson	Method	A933D0A0-D71F-4BB0-AF1B-99E9FF741832:Method Labels:"Product Name" set to "Log off set to 4 mins Test" fr
361	Keith Wilkinson	Method	A933D0A0-D71F-4BB0-AF1B-99E9FF741832:Method Re-saved: Changing its ID from "9782843B-D3E9-4768-A4C
360	Administrator	System Log On Status	User Logged Off
359	Keith Wilkinson	Method	9782843B-D3E9-4768-A40A-7DEE0EF081E3:Method Re-saved: Changing its ID from "A6EC44D0-C12C-4D8E-B-
358	Keith Wilkinson	Method	31DAB3C0-0F84-4DAF-A063-87DAECA4257A:Method Re-saved: Changing its ID from "A6EC44D0-C12C-4D8E-B-
357	Keith Wilkinson	System Log On Status	User log on successful to level "Application" in group "Default Group"
356	Administrator	System Log On Status	User Logged Off
355	Administrator	System Administration	Get the user "Keith Wilkinson" in group "Default Group" setting the group data before executing set data

23 Networking

WinDiss32-V3 uses **Oracle Database 10g™** for data storage and management. With Oracle your information is always available and secure. Oracle is the best choice for large enterprises, small and midsize businesses, and departments alike. Oracle Database 10g has unique security features that address privacy, regulatory compliance, and data consolidation requirements.

Oracle automates time-consuming, error-prone administrative tasks, so DBAs can focus on strategic business objectives with superior manageability and significant cost savings over conventional databases.

The Oracle network database provides a central relational database that contains records from **WinDiss32-V3** workstations. Results are accessible from any workstation on the company's network linked to our Oracle database.

Each **WinDis32-V3** system runs from a workstation PC, each hardware configuration can be unique.

With this configuration, records can be signed remotely from any **WinDiss32-V3** client. For example, it is now possible for analysts and supervisors or managers to view, sign, print etc away from the laboratory area.

